इंटरनेट मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”
Mazdoor Kisan Shakti Sangathan
“The Right to Information, The Right to Live”

“पुराने को छोड नये के तरफ”
Jawaharlal Nehru
“Step Out From the Old to the New”

IS 13020-1 (1991): Medical Electrical Equipment - Ultrasonic Therapy equipment, Part 1: Particular Requirements for Safety [MHD 15: Electromedical Equiment]

“ज्ञान से एक नये भारत का निर्माण”
Satyanarayan Gangaram Pitroda
“Invent a New India Using Knowledge”

Act Number 22 of 2005
The Indian Parliament
RIGHT TO INFORMATION

Made Available By
Public.Resource.Org

“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”
Bhartṛhari—Nītiśatakam
“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE

BRUTUM FULMEN

IGNORANTIA JURIS NON EXCUSAT

PROTECTED BY COPYRIGHT

IS 13020 (Part 1) : 1991

(Reaffirmed 2001)

भारतीय मानक

चिकित्सकीय विद्युत उपस्कर — पराश्रव्य उपचार उपस्कर

भाग 1 सुरक्षा के लिए विशिष्ट अपेक्षाएँ

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — ULTRASONIC THERAPY EQUIPMENT

PART 1 PARTICULAR REQUIREMENTS FOR THE SAFETY

UDC 615·837·3·614·8

© BIS 1991

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

May 1991

Price Group 3

Electromedical Equipment Sectional Committee, MHD 19

FOREWORD

This Indian Standard (Part 1) was adopted by the Bureau of Indian Standards, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

Ultrasonic therapy equipment are used extensively in medical practice. It is important to incorporate requirements of safety and performance in the equipment for the safety of the patient and the operator and also to obtain the maximum effective intensity from the equipment.

In combined equipment, this particular standard is applicable only to the ultrasonic part. However, in combined equipment, for example, where the treatment head forms one of the electrodes of an electric simmulator, earthing of the treatment head may not be allowed.

Since ultrasonic therapy equipment may be used with water during treatment, protection of the equipment against the effects of accidental spillage is necessary.

Watertightness of the treatment head is necessary not only for the ease of treatment under water, but also to prevent the ingress of oils, or creams used for coupling of the transducer face to the patient's skin during treatment outside of water bath. The depth of a immersion during the test is based on methods used in clinical practice. The requirements for protection against spillage and ingress of liquids have been specified in the standard.

This standard has been formulated into two parts; while Part 1 specifies particular requirements for the safety, Part 2 specifies performance and construction requirements. It may be noted that in addition to safety requirements specified in the various parts of IS 8607 mentioned in **2**, ultrasonic parts of the equipment may present typical hazards and, therefore, protection against unwanted ultrasound have been specified in this standard. Also, removal of the treatment head from contact with the patient is likely during treatment and may result in an increase in the temperature of the radiating surface of the treatment head. A test with the treatment head radiating into air for short periods is therefore specified. The test method specified minimises measurement errors due to the heating of the temperature measuring device by ultrasound radiation.

In the preparation of this standard, assistance has been derived from IEC 601-1-1988 'Medical electrical equipment : Part 1 General requirements for safety' and IEC 601-2·5 : 1984 'Medical electrical equipment: Part 2 Particular requirements for ultrasonic therapy equipment', issued by International Electrotechnical Commission.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT — ULTRASONIC THERAPY EQUIPMENT

PART 1 PARTICULAR REQUIREMENTS FOR THE SAFETY

1 SCOPE

1.1 This standard (Part 1) specifies the requirements for safety of ultrasonic therapy equipment used in medical practice (hereinafter referred to as equipment).

1.2 This standard does not apply to equipment in which a tool is driven by ultrasound (for example equipment used in surgery or dentistry) or in which focused ultrasound pulse waves are used to destory conglomerates such as stones in the kidneys or the bladder (lithotrites).

2 REFERENCES

2.1 The following Indian standards are necessary adjuncts to this standard:

IS No.	*Title*
8607	Medical electrical equipment — General requirements for safety
(Part 1)	Terminology (*first revision*) (*under preparation*)
(Part 2)	General (*first revision*) (*under preparation*)
(Part 3)	Environmental conditions (*first revision*) (*under preparation*)
(Part 4)	Protection against electric shock hazards (*first revision*) (*under preparation*)
(Part 5)	Protection against mechanical hazards (*first revision*) (*under preparation*)
(Part 6)	Protection against hazards from unwanted or excessive radiation (*first revision*) (*under preparation*)
(Part 7)	Protection against hazards of ignition of flammable anaesthetic mixtures (*first revision*) (*under preparation*)
(Part 8)	Protection against excessive temperatures and other safety hazards (*first revision*) (*under preparation*)

NOTE — Till such time the standard under preparation is published, the matter shall be as agreed to between the concerned parties.

3 TERMINOLOGY

3.0 For the purpose of this standard, definitions given in IS 8607 (Part 1) shall apply in addition to the following.

3.1 Applied Part

Radiating area and the other accessible parts of the treatment head, including any adaptor shall be included in the definition of the applied part.

3.2 Ultrasonic Therapy Equipment

Equipment for the generation and application of ultrasound to a patient for therapeutic purposes.

NOTE — Essentially the equipment comprises a generator of electric high-frequency power and a transducer for converting this to ultrasound.

3.3 Ultrasonic Transducer

Device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range.

3.4 Treatment Head

Assembly comprising one or more ultrasonic transducer(s) and associated parts for local application of ultrasound to the patient.

NOTE — A treatment head is also referred to as an applicator.

3.5 Adaptor

Accessory intended to be attached to the treatment head for the purpose of modifying the effective intensity and/or the effective radiating area.

3.6 Ultrasound

Mechanical oscillation, the frequency of which is above 20 kHz.

3.7 Rated Output Power

Maximum effective ultrasound output power of the equipment. It is expressed in watts.

3.8 Effective Ultrasound Output Power

Ultrasound power radiated by the treatment head in the forward direction into an approximately free field in water, under standard conditions. It is expressed in watts. In the case of modulated ultrasound radiation, the ultrasound power is averaged over at least three periods of the lowest modulation frequency.

3.9 Modulation

Periodic variation of the amplitude of an ultrasonic wave. It may be sinusoidal, pulsed, or may result from full or half-wave rectification of the mains frequency power supply. When the degree of modulation is less than 25 percent, the wave will be considered continuous.

NOTE — The degree of modulation is the quotient of the difference and the sum of maximum and minimum amplitudes of the wave.

3.10 Effective Radiating Area

In the case of treatment heads having a flat circular radiating surface it is 1.11 times the area of a particular circular baffle chosen to allow transmission of 90 percent of the effective ultrasound output power, measured near the radiating surface. It is expressed in square centimetres.

3.11 Effective Intensity

The quotient of the effective ultrasound output power and the effective radiating area. It is expressed in watts per square centimetre.

3.12 Maximum Intensity

In the case of treatment heads having a flat circular radiating surface with a diameter not less than 2 cm it is $4/\pi$ times the maximum effective ultrasound output power when measured with a circular baffle of 1 cm diameter near the centre of the radiating surface. It is expressed in watts per square centimetre.

NOTE — A definition of maximum intensity for treatment heads having smaller diameter and/or other types of radiating surface is under consideration.

3.13 Intensity Ratio

The quotient of the maximum intensity and the effective intensity of a treatment head.

3.14 Ultrasonic Frequency

The frequency of ultrasound expressed to at least two significant figures with a particular treatment head immersed in water. It is expressed in kilohertz or megahertz.

4 ENVIRONMENTAL CONDITION

4.1 Provision as given in IS 8607 (Part 3) shall apply.

5 GENERAL REQUIREMENTS

5.1 Provisions as given in IS 8607 (Part 2) shall apply.

6 GENERAL REQUIREMENTS FOR TESTS

6.1 Provisions as given in IS 8607 (Part 2) shall apply.

7 CLASSIFICATION

7.1 Provisions as given in IS 8607 (Part 2) shall apply except that equipment when classified according to the mode of operation shall be of continuous operation type only.

8 IDENTIFICATION, MARKING AND DOCUMENTS

8.0 Provisions as given in IS 8607 (Part 2) shall apply except the following:

The generator of an ultrasonic therapy equipment shall additionally be provided with markings.

8.1 Marking on the outside of equipment pertaining to output shall be, as given in **8.1.1**.

8.1.1 *Output*

Under this category following markings shall be provided:

a) The generator of an ultrasonic therapy equipment shall additionally be provided with markings:
   1) Ultrasonic frequency or frequencies in kilohertz or megahertz, and
   2) Rated output power in watts.
b) In the case of degree of modulation in excess of 25 percent of the following characteristics of the acoustic output shall be marked on the equipment or specified in the accompanying documents:
   1) degree of modulation,
   2) waveform of the modulation, and
   3) frequency of the modulation.
c) Any detachable treatment head shall be marked so that it is uniquely identified with the particular output of the generator with which it is intended to be used.

8.2 Instruction for Use

The instructions for use shall additionally contain the following:

a) Information on ultrasonic frequency or frequencies in kilohertz or megahertz and effective radiating area or areas in square centimetres of any treatment head or adaption;
b) A recommendation calling the user's attention to the need of periodic maintenance, especially,
   1) inspection of the treatment head for cracks, which may follow the ingress of conductive fluid; and
   2) inspection of the treatment head cables and associated connectors.

c) Advice on the procedures necessary for safe operation, drawing attention to the safety hazards which may occur as a result of an inadequate electrical installation;

d) Advice on the type of electrical installation to which the equipment may be safely connected, including the connection of any potential equalization conductor; and

e) The user's attention should be drawn to the need for care when handling the treatment head since rough handling may adversely affect its characteristics.

9 POWER INPUT

9.1 Provision as given in IS 8607 (Part 4) shall apply with the equipment operated as specified in this standard.

10 PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

10.0 General

Provisions as given in IS 8607 (Part 4) shall apply.

10.1 In addition in the case of combined equipment (for example ultrasonic therapy equipment additionally provided with a function or an applied part for electrical stimulation) such equipment shall also comply with any particular standard specifying safety requirements for the additional function.

11 PROTECTION AGAINST MECHANICAL HAZARDS

11.0 General

Provision as given in IS 8607 (Part 5) shall apply.

11.1 Mechanical Strength

Provision of IS 8607 (Part 5) shall apply except as follows.

11.1.1 The requirement and tests as specified in IS 8607 (Part 5) for hand held patient electrodes shall be applied to hand-held treatment heads. Additionally, the treatment head shall be tested for compliance with this standard.

12 PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

12.0 Provisions as given in IS 8607 (Part 6) shall apply except as given below.

12.1 Acoustical Energy (Including Ultrasonics)

The intensity of the unwanted ultrasound radiation from a treatment head intended for hand-held use, shall be less than 100 mW/cm^2 when measured as described in **12.1.1**.

NOTE — The figure of 100 mW/cm^2 incorporates a very high safety factor due to low efficiency of coupling to the operator's hand in normal use, in comparison with test condition. The limit for unwanted radiation power density is only about 3 percent of the power density of the intended radiation. As it is very difficult to limit the ultrasound reflection factor to 1 percent or less, reflections and/or standing waves having amplitudes in the same order of magnitude as the unwanted radiation shall be encountered which may heavily influence this measurement.

12.1.1 Compliance shall be checked by the following test:

The treatment head is immersed in degassed water the temperature of which is 35 ± 3°C. The equipment is operated at the maximum effective ultrasound output specified for the treatment head. The unwanted ultrasound radiation is measured, for example, by using a calibrated hydrophone, from all such surfaces of the treatment head which are specified to be hand-held during normal use (*see* Fig. 1).

NOTE — If the measured value exceeds the above limit, it is recommended to shift the treatment head alightly in order to detect any influence of reflections and/or standing waves on the measurement or to repeat the measurement in another (possibly larger) container.

13 PROTECTION AGAINST THE HAZARDS OF EXPLOSIVE IN MEDICALLY USED ROOMS

Provisions as given in IS 8607 (Part 7) shall apply.

14 PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS, SUCH AS HUMAN ERRORS

14.0 General

Provisions as given in IS 8607 (Part 8) shall apply except as follows.

14.1 Excessive Temperature

Provisions as given in IS 8607 (Part 8) shall apply, except as follows.

14.1.1 Compliance with this requirement of the general standard shall be checked by the following test (*see* Fig. 2).

a) The radiating surface of normally hand-held treatment head is immersed approximately 1 cm below the surface of 2 litres of water having a total depth of not less than 20 cm and an initial temperature of 25 ± 1°C. The equipment is operated for 3 min at the maximum effective ultrasound output power specified for the treatment head concerned. The treatment head is then removed from the water for 15 s and then immediately reimmersed in the water and the above cycle repeated twice more (a total test time of 9 min 45 s).

b) A treatment head which is intended only for use under water, and which is not intended to be used as a hand-held device, shall be tested while completely immersed in not less than 2 litres of water with the equipment operating for 15 min at the maximum effective ultrasound output power specified for the treatment head concerned.

14.1.1.1 At no time during the above tests shall the temperature of the radiating surface exceed 41°C.

NOTE — During the measurement of temperature, it may be necessary to de-energize the treatment head in order to avoid direct heating of the temperature measuring device.

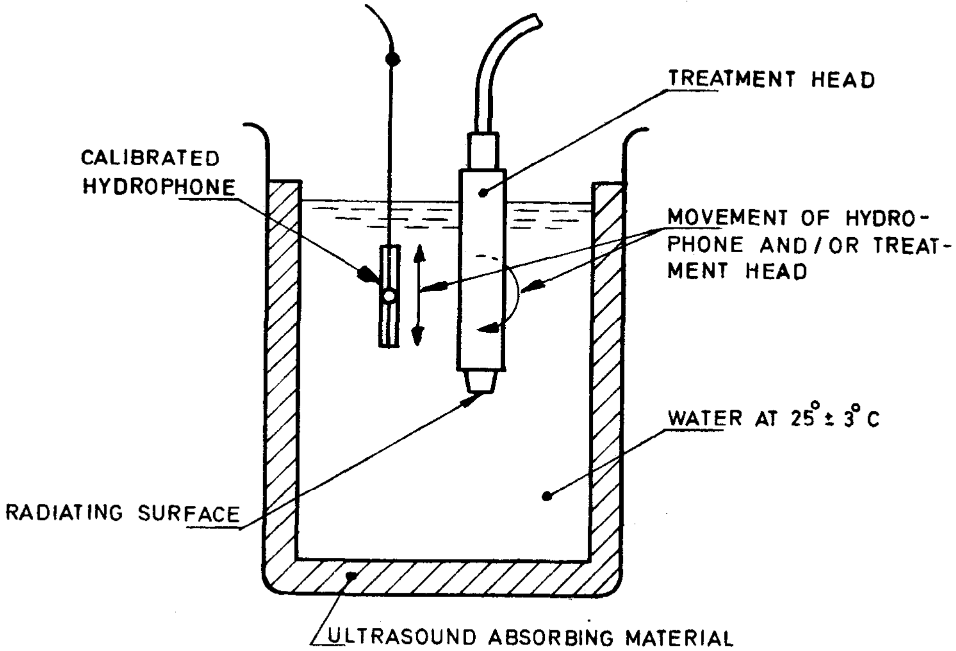
TREATMENT HEAD
CALIBRATED HYDROPHONE
MOVEMENT OF HYDRO-PHONE AND / OR TREAT-MENT HEAD
WATER AT 25° ± 3° C
RADIATING SURFACE
ULTRASOUND ABSORBING MATERIAL

FIG. 1 ARRANGEMENT FOR TESTING FOR UNWANTED RADIATION FROM THE TREATMENT HEAD

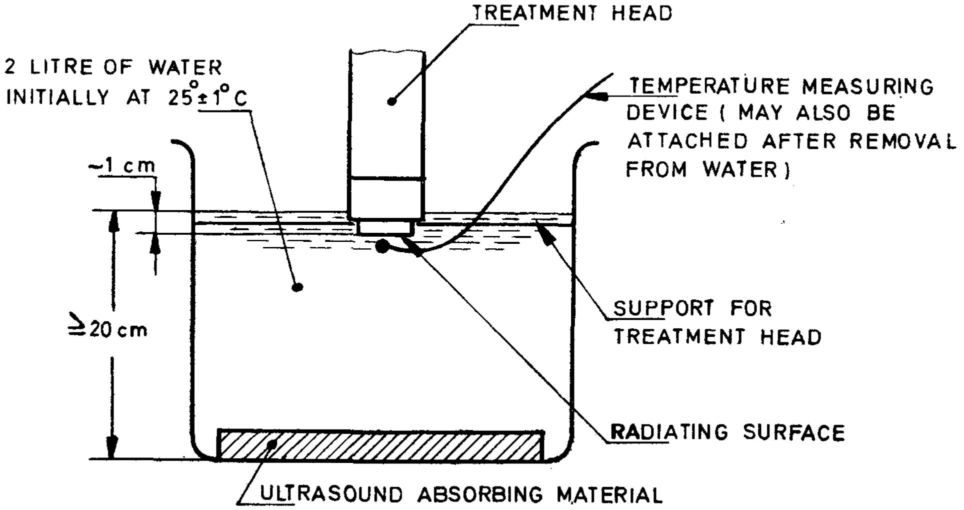
TREATMENT HEAD
2 LITRE OF WATER INITIALLY AT 25° ± 1° C
TEMPERATURE MEASURING DEVICE (MAY ALSO BE ATTACHED AFTER REMOVAL FROM WATER)
~1 cm
≥20 cm
SUPPORT FOR TREATMENT HEAD
RADIATING SURFACE
ULTRASOUND ABSORBING MATERIAL

FIG. 2 ARRANGEMENT FOR TESTING THE TEMPERATURE OF THE RADIATING SURFACE

14.2 Temperature-Rise Test

Provisions of IS 8607 (Part 8) shall apply except the following.

14.2.1 The temperature-rise test for the generator is performed with the equipment operated at its rated output power with the treatment head immersed in a container filled with water at a temperature of 25 ± 10°C for a period of time as specified in IS 8607 (Part 8).

14.3 Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization and Distinction

Provision of IS 8607 (Part 8) shall apply except as follows.

14.3.1 *Spillage*

The enclosure of ultrasonic therapy equipment shall be so constructed that in the event of liquids no safey hazard shall occur.

14.3.1.1 Compliance shall be checked by the following test :

The equipment shall be placed in the position of normal use. It is then subjected for 30 s to an artificial rainfall of 3mm/min falling vertically from a height of 0·5 m above the top of the equipment. A test apparatus as shown in IS 8607 (Part 8) shall be used. An intercepting device may be used to determine the duration of the test. Immediately after the 30 s exposure, visible moisture on the body of the equipment shall be removed.

Immediately after the above test, it shall be checked that any water which may have entered the equipment does not adversely affect the safety of the equipment. In particular, the equipment shall be capable of meeting the dielectric strength tests and the equipment shall function normally.

14.3.2 *Ingress of Liquids*

Following additional requirements shall apply.

14.3.2.1 The treatment head and ultrasonic therapy equipment shall be watertight.

Compliance shall be checked as given in IS 8607 (Part 8) but the equipment head including the inlet of the connecting cord shall be immersed in water to a depth of 20 cm.

14.3.2.2 A treatment head specified for ultra sonic therapy in combination with pressurized water massage shall withstand the maximum pressure occurring in this treatment.

Compliance shall be checked by the test mentioned in **14.3.2.1.1** above but at 1·3 times the maximum pressure occurring in normal use.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Revision of Indian Standards

Indian Standards are reviewed periodically and revised, when necessary and amendments, if any, are issued from time to time. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition. Comments on this Indian Standard may be sent to BIS giving the following reference:

Doc : No. MHD 19 (2218)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters :

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	331 01 31 331 13 75
Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola CALCUTTA 700054	87 86 62
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	53 38 43
Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113	2 35 02 16
Western : Manakalaya, E9 MIDC, Marol, Andheri (East) BOMBAY 400093	6 32 92 95

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR.
COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI.
HYDERABAD. JAIPUR. KANPUR. PATNA. THIRUVANANTHAPURAM.

Printed at New India Printing Press, Khurja, India